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PUBLIC HEALTH SERVICE
COST-SHARING AGREEMENT

This **Agreement** is entered into between the National Institutes of Health (“**NIH**”) or the Food and Drug Administration (“**FDA**”), hereinafter singly or collectively referred to as “**PHS**”, agencies of the United States Public Health Service within the Department of Health and Human Services (“**HHS**”) through the Office of Technology Transfer, **NIH**, having an address at 6011 Executive Boulevard, Suite 325, Rockville, Maryland 20852-3804, U.S.A and _____, hereinafter referred to as the “**Institution**”, having an address at _____.

1. **BACKGROUND**

- 1.1 In the course of fundamental research programs at the **PHS** and by the **Institution**, _____ (hereinafter referred to as the “**Inventor(s)**”) made or reduced to practice certain inventions, which are included within the **Patent Rights**, as defined in Paragraph 2.1.
- 1.2 It is the mutual desire of the **Institution** and the **PHS** that their respective undivided interests in the **Patent Rights** be administered in a manner to ensure the rapid commercialization of the **Patent Rights** and to make their benefits widely available to the public.
- 1.3 The Government of the United States (hereinafter referred to as “**Government**”) shall have the irrevocable, royalty-free, paid-up right to practice and have practiced the **Patent Rights** throughout the world by or on behalf of the **Government** and on behalf of any foreign government or international organization pursuant to any existing or future treaty or agreement to which the **Government** is a signatory.
- 1.4 **PHS** and the **Institution** are co-owners of the **Patent Rights** through the assignment of rights from the **Inventors**.

2. **DEFINITIONS**

- 2.1 “**Patent Rights**” means:
 - (a) Patent applications (including provisional patent applications and PCT patent applications) or patents as follows: U.S. Patent Application Serial No./U.S. Provisional Patent Application Serial No. ____/____,_____, filed _____, entitled _____, and any patent application(s) claiming the benefit of priority thereof including all divisions and continuations of these applications, all patents issuing from such applications, divisions, and continuations, and any reissues, reexaminations, and extensions of all such patents to the extent that at least one **Inventor** from the **Institution** is an **Inventor** thereon;
 - (b) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.1(a) and to the extent that at least one **Inventor** from the **Institution** is an **Inventor**:

A-XXX-200X

CONFIDENTIAL

PHS Cost Sharing Agreement

Model 10-2005 Page 1 of 6 [Draft/Final] [Company] [Date]

- (i) continuations-in-part of 2.1(a);
 - (ii) all divisions and continuations of these continuations-in-part;
 - (iii) all patents issuing from these continuations-in-part, divisions, and continuations;
 - (iv) priority patent application(s) of 2.1(a); and
 - (v) any reissues, reexaminations, and extensions of all these patents; and
- (c) to the extent that the following contain one or more claims directed to the invention or inventions disclosed in 2.1(a) and to the extent that at least one **Inventor** from the **Institution** is an **Inventor**: all counterpart foreign and U.S. patent applications and patents to 2.1(a) and 2.1(b); and
- (d) **Patent Rights** shall *not* include 2.1(b) or 2.1(c) to the extent that they contain one or more claims directed to new matter which is not the subject matter disclosed in 2.1(a).
- 2.2 “**Expenses**” means all reasonable and actual out-of-pocket costs, excluding those reimbursed by a third party, incurred by **PHS** for the preparation, filing, prosecution, and licensing of United States and foreign patent applications, extraordinary expenses as provided in Paragraph 3.6, and the maintenance of resulting the patents or patent applications, exclusive of any salaries, administrative, or other indirect costs.

3. PATENT PROSECUTION AND PROTECTION

- 3.1 **PHS** shall file, prosecute, and maintain patent application(s) relating to the **Patent Rights** and shall promptly provide to the **Institution** all serial numbers and filing dates, together with copies of all the applications, including copies of all Patent Office actions, responses, and all other Patent Office communications. In addition, the **Institution**, shall be granted Power of Attorney for all such patent applications. **PHS** shall consult with the **Institution**, when so requested, prior to communicating with any Patent Office with respect to the **Patent Rights**.
- 3.2 **PHS** shall make an election with respect to foreign filing, upon consultation with the **Institution**. If any foreign patent applications are filed, **PHS** shall promptly provide to the **Institution** all serial numbers and filing dates. **PHS** also shall provide to the **Institution** copies of foreign patent applications and Patent Office actions. **PHS** shall consult with the **Institution**, when so requested, prior to communication with any Patent Office with respect to the **Patent Rights**.
- 3.3 **PHS** shall promptly record assignments of domestic patent rights in the United States Patent and Trademark Office and shall promptly provide the **Institution** with a photocopy of each recorded Assignment(s) to the **Institution**.

- 3.4 Notwithstanding any other provision of this **Agreement**, **PHS** shall not abandon the prosecution of any patent application, including provisional patent applications (except for purposes of filing continuation application(s)) or the maintenance of any patent contemplated by this **Agreement**, without prior written notice to the **Institution**. Upon receiving the written notice, the **Institution** may, at its sole option and expense, take over the prosecution of any patent application, or the maintenance of any patent.
- 3.5 **PHS** shall promptly provide to the **Institution** copies of all patents issued which are subject to this **Agreement**.
- 3.6 In the event that **PHS** anticipates the possibility of any extraordinary expenditures arising from the preparation, filing, prosecution, licensing, or defense of any patent application or patent contemplated by this **Agreement**, including, without limitation, interferences, reexaminations, reissues and oppositions, **PHS** shall provide the **Institution** with all relevant information and these extraordinary expenditures shall be included as **Expenses** only upon written agreement of the **Institution**. **PHS** and the **Institution** shall agree on a mutually acceptable course of action prior to incurring these expenditures.
- 3.7 **PHS** or its contractors shall submit statements of itemized expenses to the **Institution**, and if the **Institution** should fail to reimburse **PHS** or its contractors for _____ percent (X%) of **Expenses** within one hundred and eighty (180) days of receipt, **PHS** may give written notice of default to the **Institution** pursuant to Paragraph 6.3. If the **Institution** should fail to cure this default within ninety (90) days from the receipt by it of the written notice, **PHS** may construe this default as termination on the part of the **Institution** pursuant to Paragraph 5.2, except where the **Institution** has identified discrepancies in billing by **PHS**, in which case payment for the contested item may be delayed pending resolution thereof.

4. LICENSING

- 4.1 The **Institution** and **PHS** shall both diligently seek licensee(s) for the commercial development of said **Patent Rights** and shall administer the **Patent Rights** for the mutual benefit of the parties and in the best interest of the public.

5. TERM AND TERMINATION

- 5.1 This **Agreement** is effective when signed by all parties, unless the provisions of Paragraph 6.8 have not been fulfilled, and shall extend to the expiration of the last to expire of the patents included within the **Patent Rights** unless otherwise terminated by operation of law or by acts of the parties in accordance with the terms of this **Agreement**.
- 5.2 The **Institution** may terminate this **Agreement** upon at least sixty (60) days written notice to **PHS**, but in any event not less than sixty (60) days prior to the date on which any pending Patent Office actions need be responded to in order to preserve **Patent Rights** for the benefit of the parties hereto.
- 5.3 **PHS** may terminate this **Agreement** for any reason upon sixty (60) days written notice to the **Institution**

A-XXX-200X

CONFIDENTIAL

PHS Cost Sharing Agreement

Model 10-2005 Page 3 of 6 [Draft/Final] [Company] [Date]

6. GENERAL

- 6.1 This **Agreement** shall be construed in accordance with U.S. Federal law, as interpreted and applied by the U.S. Federal courts in the District of Columbia. Federal law and regulations shall preempt any conflicting or inconsistent provisions in this **Agreement**. **Institution** agrees to be subject to the jurisdiction of U.S. courts.
- 6.2 Any controversy or any disputed claim by either party against the other arising under or related to this **Agreement** shall be submitted jointly to the **Institution's** President or designee and to the Director of the **NIH** or designee for resolution. The **Institution** and **PHS** shall be free after written decisions are issued by those officials to pursue any and all administrative or judicial remedies which may be available.
- 6.3 All **Agreement** notices required or permitted by this **Agreement** shall be given by prepaid, first class, registered or certified mail or by an express/overnight delivery service provided by a commercial carrier, properly addressed to the other party at the address designated on the following Signature Page, or to another address as may be designated in writing by the other party. **Agreement** notices shall be considered timely if the Notices are received on or before the established deadline date or sent on or before the deadline date as verifiable by U.S. Postal Service postmark or dated receipt from a commercial carrier. Parties should request a legibly dated U.S. Postal Service postmark or obtain a dated receipt from a commercial carrier or the U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.
- 6.4 It is agreed that no waiver by either party hereto of any breach or default of any of the covenants or agreements herein set forth shall be deemed a waiver as to any subsequent or similar breach or default.
- 6.5 This **Agreement** is binding upon and shall inure to the benefit of the parties hereto, their successors or assigns, but this **Agreement** may not be assigned by either party without the prior written consent of the other party.
- 6.6 Any modification to this **Agreement** must be in writing and agreed to by both parties.
- 6.7 It is understood and agreed by the **Institution** and **PHS** that this **Agreement** constitutes the entire agreement, both written and oral, between the parties, and that all prior agreements respecting the subject matter hereof, either written or oral, expressed or implied, shall be abrogated, canceled, and are null and void and of no effect.
- 6.8 The terms and conditions of this **Agreement** shall, at **PHS'** sole option, be considered by **PHS** to be withdrawn from **Institution's** consideration and the terms and conditions of this **Agreement**, and the **Agreement** itself to be null and void, unless this **Agreement** is executed by the **Institution** and a fully executed original is received by **PHS** within sixty (60) days from the date of **PHS** signature found at the Signature Page.

SIGNATURE PAGE

IN WITNESS WHEREOF, the parties hereto have executed this **Agreement** in duplicate originals by their respective duly authorized officers hereunto, on the day and year hereinafter written. Any communication or notice to be given shall be forwarded to the respective addresses listed below.

For **PHS**:

Steven M. Ferguson
Director, Division of Technology Development and Transfer
Office of Technology Transfer
National Institutes of Health

Date

Mailing Address for **Agreement** notices:

Chief, Monitoring & Enforcement Branch, DTD
Office of Technology Transfer
National Institutes of Health
6011 Executive Boulevard, Suite 325
Rockville, Maryland 20852-3804 U.S.A.

For the **Institution** (Upon information and belief, the undersigned expressly certifies or affirms that the contents of any statements of the **Institution** made or referred to in this **Agreement** are truthful and accurate.)
by:

Signature of Authorized Official

Date

Printed Name

Title

Official and Mailing Address for **Agreement** notices:

A-XXX-200X

CONFIDENTIAL

PHS Cost Sharing Agreement

Model 10-2005 Page 5 of 6 [Draft/Final] [Company] [Date]

Official and Mailing Address for Financial notices (**Licensee's** contact person for royalty payments)

Name

Title

Mailing Address:

Email Address: _____

Phone: _____

Fax: _____

Any false or misleading statements made, presented, or submitted to the **Government**, including any relevant omissions, under this **Agreement** and during the course of negotiation of this **Agreement** are subject to all applicable civil and criminal statutes including Federal statutes 31 U.S.C. §§3801-3812 (civil liability) and 18 U.S.C. §1001 (criminal liability including fine(s) or imprisonment).

A-XXX-200X

CONFIDENTIAL

PHS Cost Sharing Agreement

Model 10-2005 Page 6 of 6 [Draft/Final] [Company] [Date]